REMARKS

Claims 1-15 and 20-21 are pending. Claims 1, 2, 12, 15, and 21 have been amended.

Claims 12-15 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Claims 1 and 4-6 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by EP 0 405 284 A2 to Greiner. Claims 1-15 and 21-22 also stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 6,153,252 to Hossainy et al., in view of U.S. Patent No. 5,833,891 to Subramaniam et al. Claims 3, 7, 9, 11, and 21-22 also stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Greiner. Claim 10 stands rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Greiner over Hossainy. Claims 2, 8 and 12-15 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Greiner in view of U.S. Patent No. 5,916,585 to Cook et al.

35 U.S.C. § 112

The Office Action rejected claims 12-15 under 35 U.S.C. § 112, arguing that "the specification, while being enabling for coating, does not reasonably provide enablement for treating." Treating is defined in *The American Heritage College Dictionary*, 3rd Ed. as "[t]o act or behave in a specified manner toward." Thus, in the context of patent claims, treating simply means to act in the manner defined by the claim after the word comprising. The Office action objects, first arguing that "[t]he specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims," and then surmising that the "specification is limited to coating medical devices with a therapeutic agent [and that] ... [t]he claims, as written require only treating the medical device ... there is no active step of coating the medical device with the therapeutic agent."

In response, undersigned submits that the teaching of the specification is not so limited and that there is ample support within the specification for rejected claim 12 as previously and currently written. First, the specification is clear that multiple coating scenarios are plausible within the spirit and scope of the invention. See ¶ 32. Second, the specification at paragraph 27

actually describes a process that does not recite the affirmative step of transferring agent to the medical device. Instead, paragraph 27 describes how one of the results of swelling the coating may be that the coating is better able to receive therapeutic. In other words, while transfer of therapeutic may be the result of the steps when carried out, the affirmative steps of the described process does not call for the transfer of therapeutic. What it does call for, placing a coated stent on a support, swelling the coating of the stent, and exposing the enlarged coating with a supercritical fluid that has been previously interfaced with a therapeutic, provides clear support for claim 12 as previously and currently written. At least based on these disclosures, there is ample support for claim 12 in the specification. Reconsideration is, therefore, requested.

For the record, the undersigned did not state that "the claims were not to be read in light of the specification" as stated in the Office Action. Rather, the relevant portion of the Response to the August 4, 2003, Office Action simply states that "[c]laim 12 is entitled to its broadest interpretation under the law and should not be read to include limitations from the specification. Put another way, the claim and not the specification defines what the claim claims."

35 U.S.C. § 102

Claims 1 and 4-6 are rejected as being allegedly anticipated by Greiner. The undersigned submits that these claims are patentable over Greiner at least because Greiner fails to disclose or suggest "transporting, within a conduit, the interfaced therapeutic and supercritical fluid," as recited in claim 1. Each of the examples in Greiner and the specification itself regards the mixing of the therapeutic and the supercritical fluid in a reactor through the use of heat and pressure (*see, e.g.*, col. 5 at 17-21). Nowhere in Greiner is a mix of supercritical fluid and therapeutic transported within a conduit. In addition, with regard to claim 6, the Office action is incorrect in that Greiner also fails to disclose or suggest having a therapeutic colloidally suspended in a supercritical fluid. The notion that "it appears that the solution in Greiner meets the definition of a colloid, in that particles of the agent are mixed with a solvent to form the solution," as asserted in the Office action, is misplaced. For one, the fact that the supercritical fluid is consistently called a solvent within Greiner shows that the therapeutic is dissolved and not colloidally suspended within the fluid. Reconsideration, therefore, is requested.

35 U.S.C. § 103

Claims 1-15 and 21-22 stand improperly rejected under 35 U.S.C. 103. For one, the references have been improperly combined. Furthermore, the cited references at least each file to disclose or suggest "interfacing a therapeutic with a supercritical fluid upstream of a control valve" as in claim 1; "swelling the coating on the medical device prior to exposing the coating on the coated medical device to the supercritical fluid that has been interfaced with the therapeutic," as in claim 12; "applying a vacuum force to a chamber containing the medical device," as in claim 21; and "reusing the residual therapeutic by interfacing the residual therapeutic with a supercritical fluid," as in claim 22. For at least each of these reasons the undersigned submits that the claims are patentable over the cited references.

With regard to claims 12 and 15, the undersigned also submits that the Office action has failed to identify a reference that contains each of the limitations from the claims. Hossainy is incorrectly cited for the act of exposing a coating on a medical device to a supercritical fluid. Nowhere, however, in Hossainy are supercritical fluids disclosed or suggested. Thus, any rejection predicated on this notion, including the Office action's citation to the previous Office action, is flawed.

Furthermore, with regard to claim 21, Subramaniam does not disclose or address "applying a vacuum force to a chamber containing the medical device." Nowhere is a vacuum discussed in Subramaniam, nor can it be read to infer that it does. To this end, the Office action states that "looking at Figure 2, it is seen that outlet 122 is more than halfway up the chamber wall ... [s]ince Subramaniam teaches an active step of removing liquid ... it is Examiner's position that this solution is not passively removed ... it would have been obvious ... to use a pump." This, however, infers too much from Subramaniam and simply uses the applicant's disclose as a road map. The chamber in Figure 2 is under pressure from the gasses being pumped into it. Accordingly, the relief line 122 could be anywhere in the chamber and continue to function to "remove" the CO_2 from chamber 120. The lack of necessity for a vacuum is reinforced by the fact that Figure 2 does not contain a vacuum pump in line 122, that the line leaving the chamber 120 (no. 122) is metered through a valve 154, and that other portions of the

system which do require a pump are so drawn, see 144. Thus, Subramaniam does not inherently disclose or suggest a vacuum as argued by the Office action.

With regard to claim 22, the Office action has also failed to even cite a reference that discloses or suggests "reusing the residual therapeutic by interfacing the residual therapeutic with a supercritical fluid." The cited portion of Subramaniam misses this point as it does not regard the reuse of therapeutic from the CO_2.

With regard to the specific rejections of claims 3,7, 9, 11 and 21-22, the undersigned requests support for the assertion that the "interchangeability of dipping and spraying as coating techniques is well known in the art of chemical coating," and the assertion that "recycling expensive therapeutic agents would have been obvious," if these assertions are maintained in the next Office action. Likewise, the undersigned also requests support for the Office action's assertions that "one of ordinary skill in the art would collect the excess solution to recover the expensive pharmaceutical agents therein for a subsequent coating operation .. A pump would be required to move solution, which inherently draws a vacuum [t]he use of a pump would have been obvious to one of skill in the art," if these assertions are maintained in the next Office action.

CONCLUSION

The claims are patentable over the cited references for at least the proceeding reasons. Reconsideration in light of the proceeding remarks is requested.

Should the Examiner have any questions regarding this submission, she is invited to contact the undersigned at 202-220-4311.

Respectfully submitted,

Dated: March 17, 2004

Fred T. Grasso
Registration No. 43,644

KENYON & KENYON
1500 K Street, N.W., Suite 700
Washington, DC 20005
(202) 220-4311 (Direct)
(202) 220-4201 (Facsimile)

DC01 482382 v 1